REMARKS

Amendments

Claims 30, 32 and 39 have been amended, and claims 30 and 32-39 are pending.

Rejections

Rejections under 35 U.S.C. § 101

The Examiner has rejected claims 30 and 32-39 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility for the reasons of record.

Applicant does not agree. Amended claim 32 is drawn to a transgenic mouse whose genome comprises a null allele of the endogenous melanocyte stimulating hormone receptor gene, wherein said endogenous gene encodes mRNA comprising a polynucleotide sequence of SEQ ID NO:19, wherein said null allele comprises a polynucleotide sequence encoding a selectable marker.

1. The Utility Requirement

Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery.

According to the Federal Circuit:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. See Brenner v. Manson, 383 U.S. 519, 534, 16 L. Ed. 2d 69, 86 S. Ct. 1033 (1966); Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention "is incapable of serving any beneficial end").

(*Juicy Whip v Orange Bang*, 185 F.3d 1364; 51 U.S.P.Q.2d 1700 (Fed. Cir. 1999)(emphasis added)).

2. Well-Established Utility

According to 35 U.S.C. § 101, "[w]hoever invents . . . any new and useful . . . composition of matter may obtain a patent therefore. . . . "

Under the Patent Office's Utility Requirement Guidelines:

> If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

Applicant submits that in light of arguments of record, a person of ordinary skill in the art would immediately appreciate why the invention is useful. Thus, it cannot be reasonably debated that a person of ordinary skill in the art would not immediately appreciate why the invention is useful: for determining gene function.

3. Substantial Utility

The Examiner argues that the asserted utilities are not substantial.

According to the MPEP:

> A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. . . . the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. See, e.g., Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "substantial" utility.

(MPEP § 2107.01 I)(emphasis added).

The MPEP additionally provides:

> Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

(MPEP § 2107.01, I). Thus, the cited portions of the MPEP guidelines relate to the situation where further research is required to establish or confirm any utility. Such is not the case here. Knockout mice have a well-known use in the study of gene function. In the present case, the present invention does not require further research to establish a utility. Applicant has provided an *in vivo* model for studying the function of the melanocyte stimulating hormone receptor gene. The Applicant has provided an immediate benefit to the public. Whether additional research is required to identify drugs capable of targeting the gene is irrelevant to whether the claimed invention has satisfied the utility requirement.

Commercial use and acceptance is an important indication that the utility of an invention has been recognized by one of skill in the art ("A patent system must be related to the world of commerce rather than to the realm of philosophy." *Brenner v Manson*, 383 U.S. 519, 148 U.S.P.Q. 689, 696 (1966)). Commercial use of the knockout mice produced by Assignee Deltagen has been clearly established. The claimed mouse has been extensively analyzed using the tests set forth in the Examples. This data has been incorporated into Deltagen's commercial database product, DeltaBase. This database has been subscribed to by at least three of the world's largest pharmaceutical companies, Merck, Pfizer and GSK. In addition, at least one (1) large pharmaceutical company has ordered the presently claimed mouse. This acceptance more than satisfies the practical utility requirement of section 101 as **it cannot be reasonably argued that a claimed invention which is actually being used by those skilled in the art has no "real world" use**. (see, for example, Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278, 6 U.S.P.Q.2d 1065, 1104 (D. Del. 1987), *aff'd*, 865 F.2d 1247, 9 U.S.P.Q.2d 1461 (Fed. Cir. 1980)("lack of practical utility cannot co-exist with infringement and commercial success); (Lipscomb's Walker on Patents, §5:17, p. 562 (1984)("Utility may be evidenced by sales and commercial demand.")

The Examiner argues that Phillips does not apply because there is no infringement of the claimed invention. Applicant submits that if the patent issued, in the absence of a license, the pharmaceutical company's use of the mouse would infringe the claims of the issued patent. The

principles discussed in Phillips are applicable here: lack of practical utility cannot co-exist with actual use of the claimed invention.

4. Specific Utility

The Examiner states that the asserted uses are not specific.

According to the MPEP, "specific utility" means "specific" to the subject matter claimed as compared to a "general utility" that would be applicable to the broad class of the invention (MPEP 2107.01). Use of the melanocyte stimulating hormone receptor -/- mouse to study the function of the gene. The Examiner is respectfully requested to explain how all other knockout mice would be used to study the function of the melanocyte stimulating hormone receptor gene.

In addition, the mice within the scope of claim 37 contain a *lacZ* gene. Their use in studying gene expression is clearly recognized by those skilled in the art:

> **Null-reporter alleles should be created**
> The project should generate alleles that are as uniform as possible, to allow efficient production and comparison of mouse phenotypes. The alleles should achieve a balance of utility, flexibility, throughput and cost. A null allele is an indispensable starting point for studying the function of every gene. Inserting a reporter gene (e.g., P-galactosidase or green fluorescent protein) allows a rapid assessment of which cell types normally support the expression of that gene.

(Austin et al., Nature Genetics (2004) 36(9):921-24, 922)(emphasis in original; emphasis added)(copy attached). As cited in Austin, and as is well known by one of ordinary skill, the purpose of expression analysis is to determine where the gene is expressed.

As is well understood in the art, the *lacZ* gene is inserted into the endogenous gene. In this case, the *lacZ* gene was inserted into the locus of the melanocyte stimulating hormone receptor gene. Expression is driven by the endogenous promoter. Expression of the *lacZ* gene indicates where the gene is expressed. This use is specific for this mouse – knockout mice in general cannot be used for this purpose. The Examiner is respectfully requested to explain how all other knockout mice would be used to study expression of the melanocyte stimulating hormone receptor gene.

5. Summary

In summary, Applicant submits that the claimed transgenic mouse, regardless of any disclosed phenotypes, has inherent and well-established utility in the study of the function of the

gene, and thus satisfies the utility requirement of section 101. Moreover, Applicant believes that the transgenic mice are useful for studying melanocyte stimulating hormone receptor gene function with respect to the cited phenotypes, for studying gene expression, and are therefore useful for a specific practical purpose that would be readily understood by and considered credible by one of ordinary skill in the art.

In light of the arguments set forth above, Applicant does not believe that the Examiner has properly made a *prima facie* showing that establishes that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the Applicant to be specific and substantial. (*In re Brana*; MPEP § 2107).

Rejections under 35 U.S.C. § 112, 1st paragraph

Claims 30 and 32-39 have been rejected for lack of enablement, as the claimed invention allegedly lacks utility. As set forth above, it the Applicant's position the claimed invention satisfies the utility requirement and therefore one skilled in the art would clearly know how to use the invention. Applicant submits that the claims as amended are fully enabled. Withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. § 112, 2nd paragraph

Claim 30 and 32-39 stand rejected as allegedly being indefinite.

The Examiner argues that the recitation of "mRNA comprising a polynucleotide of SEQ ID NO:19" is indefinite because SEQ ID NO:19 is DNA.

Applicant respectfully disagrees. SEQ ID NO:19 corresponds to X65635, which according to NCBI, is mRNA.

The Examiner argues that recitation of "wherein said endogenous allele encodes" is indefinite.

The claim has been amended to clarify that the endogenous gene (wild-type) comprises the recited polynucleotide.

Claim 30 is objected to on the ground that a pseudopregnant mouse cannot give birth. Contrary to the Examiner's assertion, as shown in the literature (see, for example, Molecular Biology of the Cell (Albert, 4th ed., Garland Science (2002)(p. 542, Figure 8-70)(copy previously

provided), the pseudopregnant female gives "birth" to the chimeric mouse. The terminology would be clearly understood by one skilled in the art.

Claim 39 has been amended to correct the typographical error.

Applicant submits that the claims as amended are definite, and respectfully request withdrawal of the rejection.

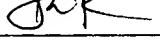
In view of the above amendments and remarks, Applicant respectfully requests reconsideration and a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. **502775**.

Respectfully submitted,

7-28-05

Date



John E. Burke, Reg. No. 35,836
Greenberg Traurig LLP
1200 17th Street, Suite 2400
Denver CO 80202
(303) 685-7411
(720) 904-6111 (fax)